

Office Action Summary

Application No.

09/980,370

Applicant(s)

COLLYER ET AL.

Examiner

Laurie Mayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15-19 is/are rejected.
- 7) ☒ Claim(s) 14 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 12 is acknowledged.

The examiner withdraws the restriction requirement and claims 1-20 are examined herein.

Specification

The use of the trademarks "PERKIN ELMER" (p. 37, line 17) and "TITERTEK TWINREADER" (p.39, line 22) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The disclosure is objected to because it contains an embedded hyperlink (p. 46, line 15) and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Information Disclosure Statement

The listing of references in the specification on pages 52-55 is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15 and 16 provide for the use of a gingipain in the manufacture of a medicament for the treatment of P. gingivalis infection, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims Objections

Claim 16 is objected to as the language "HA2-containingmolecule" is missing a space between the words. Appropriate correction is required.

Claims 14 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 15 and 16 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper

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definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Bramanti et al. (cited in paper # 10). Bramanti et al. teach agents, namely, protoporphyrin IX and zinc protoporphyrin (table 2) in distilled water stock solutions (p. 7413 (col. 2, last para.))(present claim 17) that antagonize the interaction between *P. gingivalis* and hemin, the crystalline chloride of heme (present claims 12, 13). Thus Bramanti et al. teach all of the elements of claims 12, 13 and 17 and these claims are anticipated under 35 USC 102(b).

Claim 15 is rejected under 35 USC 102(b) as being anticipated by Potempa et al. (WO 97/34629). Potempa et al. teach a method of using a gingipain in the manufacture of a medicament for the prevention or treatment of *P. gingivalis* infection (p. 3, lines 1-5 and 20-25) (present claim 15). Thus Potempa et al. teach all of the elements of claim 15 and this claim is anticipated under 35 USC 102(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-6, 9, 15, 16, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Potempa et al. in view of Nakayama et al. (cited in IDS, paper # 6) and Bramanti et al. Potempa et al. teach a method of using a gingipain (present claims 6, 15, 16, 19), which contains HA2 domain which comprises an amino acid sequence corresponding to a nucleotide sequence with 99.25% identity to SEQ ID NO: 5 (see p. 68-73 and copy of attached sequence alignment)(present claim 9), in the manufacture of a medicament for the prevention or treatment of *P. gingivalis* infection in the oral cavity in humans (p. 3, lines 1-5 and 20-25) (present claims 3-5, 15, 18). Potempa et al. do not describe an agent which antagonizes the interaction between a molecule derived from *P. gingivalis* and an HA2-binding motif on a porphyrin containing molecule.

Nakayama et al. teach that *P. gingivalis* contributes to adult periodontitis and that *P. gingivalis* binds to heme and requires heme or hemoglobin for its growth. (p. 51, col. 2, 3rd para. to p. 52, col. 1.) (present claims 6, 7, 10, 19). Nakayama et al. do not teach

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an agent which antagonizes the interaction between a molecule derived from *P. gingivalis* and an HA2-binding motif on a porphyrin containing molecule.

Bramanti et al. teach agents, namely, protoporphyrin IX and zinc protoporphyrin (table 2) that antagonize the interaction between *P. gingivalis* and hemin, the crystalline chloride of heme (present claims 7, 8, 12, 13). Bramanti et al. do not teach a method of administering these agents to treat infection caused by *P. gingivalis*. Given the social desirability of treating diseases caused by *P. gingivalis* as taught by Potempa et al., the dependency of *P. gingivalis* on interacting with a porphyrin containing molecule as taught by Nakayama et al., and the ability of protoporphyrin IX and zinc protoporphyrin to antagonize the interaction between *P. gingivalis* and hemin, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the agents taught by Bramanti et al. or to use an agent to antagonize a molecule derived from *P. gingivalis* containing and HA2 domain and an HA2-binding motif on a porphyrin containing molecule, such as heme or hemin to treat disease caused by *P. gingivalis*. Thus, the claimed invention was prima facie obvious to make and use at the time the claimed invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Progulske-Fox et al. (WO 96/17936) in view of Nakayama et al. (cited in IDS, paper # 6) and Bramanti et al. Progulske-Fox et al. teach a method of using an hagA gene (SEQ ID NO: 1) and an HA2-containing molecule comprising an amino acid sequence with 100% identity to SEQ ID NO: 1 (see claim 4 and copy of attached sequence alignment), in the manufacture of a medicament for the prevention or treatment of *P. gingivalis* infection in the oral cavity in humans (see claim 1). Progulske-Fox et al. do not describe an agent

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which antagonizes the interaction between a molecule derived from *P. gingivalis* and an HA2-binding motif on a porphyrin containing molecule specifically.

Given the social desirability of treating diseases caused by *P. gingivalis* as taught by Progulske-Fox et al. the dependency of *P. gingivalis* on interacting with a porphyrin containing molecule as taught by Nakayama et al., and the ability of protoporphyrin IX and zinc protoporphyrin to antagonize the interaction between *P. gingivalis* and heme, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the agents taught by Bramanti et al. or to use an agent to antagonize a molecule derived from *P. gingivalis* containing and HA2 domain and an HA2-binding motif, whether heme, heme, hemoglobin and salts thereof, on a porphyrin containing molecule, such as heme or heme to treat disease caused by *P. gingivalis*. Thus, the claimed invention was prima facie obvious to make and use at the time the claimed invention was made.

Conclusion

Claims 14 and 20 are objected to. Claims 1-13 and 15-19 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached on Monday through Friday from 9 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers

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for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

Laurie Mayes
Patent Examiner
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June 30, 2003